REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 1-7 are pending in the present application. Claims 1-7 have been amended to address several informalities. In addition, claim 6 has been amended to recite that the clopidogrel and clopidogrel hemisulfate has a purity level approximately equal to or higher than 99%. Support for this amendment may be found in the present specification of page 4, line 6 to 7.

In the outstanding Official Action, claim 6 was rejected under 35 USC 102(b) as allegedly being anticipated by Aubert, Badore or Bousquet. Applicant believes that the present amendment obviates this rejection.

Applicants believe that Aubert, Badore and Bousquet all fail to disclose or suggest a highly purified clopidogrel or clopidogrel hemisulfate as set forth in the claimed invention. Applicants believe that none of the cited publications teach the claimed purity level.

While Aubert is directed to the purification of the clopidogrel, Aubert fails to provide any information as to the purity degree of the salt. Moreover, no information is given as to the purity degree of clopidogrel freebase.

As to Badore, Badore discloses the preparation of a (+) - clopidogrel and (+) - clopidogrel hemisulfate having a specific rotary power (a_{20}) of +51.52 and + 55+10, respectively. These values are directed to the optical purity, i.e. the ratio of the destro and levo isomers, not the purity level of the final product.

Bousquet also relates to the preparation of clopidogrel. However, the Examiner's attention is respectfully directed to Example 14, wherein the optical purity of the clopidogrel is 96%, while Example 15 relates to (S) clopidogrel hemisulfate having a specific rotary power of 53°, Bousquet does not give any information concerning the purity degree of the final products.

Thus, in view of the above, Applicants believe that Aubert, Badore and Bousquet fail to disclose or suggest the claimed invention.

Claims 1-4 and 7 were rejected under 35 USC 103(a) as allegedly being unpatentable over Aubert, Badore or Bousquet, in view of Berge and/or Barth. This rejection is respectfully traversed.

In opposing the rejection, the Official Action alleges that at the time of the present invention, one of ordinary skill in the art would have been motivated to replace the non-FDA approved hemisulfate sought of Badore or Bousquet with the FDA

approved methyl sulfate as taught by Berge and/or Barth in order to obtain the claimed invention.

The Examiner' attention is respectfully reminded that the technical problem underlying the present invention is not to find another pharmaceutically acceptable clopidogrel salt, but to provide a clopidogrel salt which does not adsorb or adsorbs less humidity. None of the above cited prior art documents addresses this technical problem, nor do they give any suggestions which would have led the skilled person to consider them as a useful starting point for the conception of the invention.

In addition, Berge discloses 53 FDA approved commercially marketed salts without giving any suggestion as to the selection of the methylsulfate salt.

As far as Barth is concerned, Barth refers to pyrazole derivates of formula (I) having a chemical structure and a biological activity different from clopidogrel (the compounds of formula (I) are antagonists of the cannabinoid receptor), therefore the skilled person would have not chose it as a starting point for the conception of the present invention. Moreover, Barth (column 2, lines 37-43) reports a list of 16 pharmaceutically acceptable salts of the compounds of formula (I), without giving any hint that would make an expert pharmaceutical chemist think that the methylsulfate salt is preferred.

Thus, in view of the above, Applicants believe that Barth fails to provide necessary motivation to combine and modify the publications of Aubert, Badore or Bousquet in a manner so as to obtain the claimed invention.

Thus, in view of the above, Applicants believe that the proposed combination for both-identified publications fail to render obvious claims 1-4 and 7.

At this time, Applicants note that claim 5 is currently withdrawn from consideration. As Applicants believe that none of the cited publications, alone or in combination with each other, disclose or suggest the claimed invention, Applicants request that claim 5 be rejoined with claims 1-4 and 6-7. Indeed, as the Examiner's aware, when Applicant elects claims directed to the product and the claim are subsequently found allowable, withdrawn process claims which depend from or otherwise include the recitations of the allowable product will be rejoined pursuant to MPEP §821.04.

The Examiner's attention is also respectfully directed to the appendix, wherein the certified copy of the Italian Priority Application No. MI2002A002228 is attached with this amendment. As a result, Applicants believe that the present application now satisfies the requirements of 35 USC §119(b).

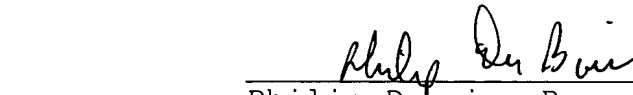
In view of the present amendment and foregoing remarks, therefore, Applicants believe that the present application is in condition for allowance at the time of the next Official Action.

Allowance and passage to issue on this basis is respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON



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APPENDIX:

The Appendix includes the following item:

☒ - a certified copy of a foreign priority document (Italy - MI2002A002228 filed October 21, 2002)